REMARKS

This is responsive to the Office Action of April 18, 2007. Reconsideration and reexamination are respectfully requested.

The present invention relates to a unique data carrier that makes it easier to keep the prescriptions and other information of a patient confidential. The Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule created national standards to protect individuals' medical records and other personal health information. Further, most health care facilities take steps to make sure patient information is not retrievable by unauthorized individuals from discarded documents, records, and other materials containing identifiable patient information. Many organizations now require that such materials be shredded or incinerated to avoid the risk of disclosure. The kinds of materials that carry identifiable patient information may include empty plastic pill vials, discarded patient ID bracelets, and used plastic bags bearing patient labels. The present invention provides an improved way of maintaining patient information in confidence.

The present invention contemplates a number of embodiments, one of which is shown in Fig. 3 of the drawings in the present application. As shown in Fig. 3, data carrier 10 includes a health information label 14, and a masking label 28. The data carrier is configured to permit the association between the name of the patient ("John Doe" in the example) and the health related information ("Amoxicillin 250 mg" in the example) to be obscured when the data carrier is about to be discarded. The data carrier includes a release liner 12. The health information label 14 has an upper surface 16 and a lower surface, and a pressure sensitive adhesive coating on the lower surface of the health information label 14 which secures the health information label to the release liner 12. The health information label 14 is made up of a first portion 18 and a second portion 20, with the first and second portions being separated by a line 22 of die cut perforations 22. Alternatively, die cut line 22 may be a continuous die cut. The label 14 includes a first area 24 on the upper surface 16 for indicia specifying health related information, such as an identification of medication, and a second area 26 on the upper surface 16 for indicia specifying the identity of a patient.

Beneath the masking label 28 is a die cut 34 in the release liner defining a removable liner piece 36. The removable liner piece 36 is removed from the release liner with the health information label 14 and remains with it when the health information label 14 is applied to a surface, such as for example the outer surface of a pharmaceutical container. When used in this manner, the liner piece 36 remains between the label 14 and the container surface and is surrounded along three edges by adhesive that secures the lower surface of the label 14 to the container surface. When the container is emptied and about to be discarded, the masking label 28 is removed from the liner piece 36 so that the masking label 28 can be applied over one or both of the first and second areas 24 and 26 to obscure the association between the name of the patient and the health related information.

The pressure sensitive adhesive coating on the lower surface of the label 14 may comprise a permanent adhesive. By this arrangement, applying the masking label 28 over one or both of the first and second areas 24 and 26 obscures the association between the name of the patient and the health related information when the data carrier is to be discarded. Because the adhesive is permanent, an attempt to remove the masking label 28 from the health information label 14 will result in the destruction of the label 14 to a degree needed to render the covered information illegible.

The Examiner has rejected claims 1, 2, 4, 6, 13 and 15 under 35 U.S.C. §112, second paragraph, as indefinite. The Examiner objects to the language in the preambles of the claims relating to HIPPA compliance, arguing that the statute may be amended at some point in the future, altering the meaning of HIPPA compliance, and changing the scope of the claims. It is submitted that the general reference in the preambles of claims 1 and 13 to HIPPA does not limit the scope of these claims, and therefore a change in HIPPA would not impact the scope of the claims. The claims were definite as originally presented. However, in order to move prosecution forward, and because the general, non-limiting reference to HIPPA is not needed in the claims, this language has been deleted. It is submitted that this rejection is now obviated.

Claims 1, 2, 4, 13 and 15 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Blank (US 7,048,308). The Blank reference is relied upon in rejecting these claims conjunction with the citation of *In re Gulack*, 217 USPQ 401 (Fed.Cir. 1983).

As shown in FIG. 3 of Blank, the main label 14 including a central portion, termed a central tab 32, is initially removed from the liner 18 to expose the adhesive 20 on the back side of the label rim. Note that no adhesive is exposed on the back side of the tab 32 by virtue of a liner tab 40. The label is adhered to a pharmaceutical container 26 using the exposed adhesive 20 around the label rim. The face side of the main label 14 and its central tab 32 expose to view all of the patient information, including the information which it is desired to keep confidential.

When container 26 is emptied, before it is discarded, the confidential information 30 is removed from the container by simply tearing away the printed tab 32 from the label rim 34. The rim 34 remains permanently bonded to the container. The slits 36 in the main label provide a convenient means for initiating tearing of the label tab 32 from the remaining label rim. The liner 18 includes a diecut 38, spaced inboard from the perimeter of the liner to define a central liner tab 40. The liner tab 40 is laminated to and corresponds substantially in size and configuration with the label tab 32. The liner tab 40 does not permit the printed tab 32 to act as a masking label, since the liner tab 40 remains permanently adhered to the printed tab 32. Additionally, the printed tab 32 could not be used as a masking label since its adhesive layer is covered by the liner tab 40, and also since the patient information that should be masked is in fact carried on the printed tab 32. It is submitted that the claims clearly define these distinctions.

The Examiner relies on *In re Gulack* as a justification for ignoring claim limitations that recite the type of information that is printed in printed in first and second areas of the health information label, and where those areas are located. As such, the Examiner distorts the holding of *In re Gulak*, and ignores its facts. *In re Gulak* did not broadly hold that printed matter claim limitations may be ignored in assessing the patentability of the claim. In fact, it held just the opposite. The invention of *In re Gulack*, in point of fact, was held to be patentable over the prior art precisely because the claims included limitations to printed matter that were not ignored and that distinguished those claims from the prior art. *In re Gulack* dealt with a "band," such as an

endless loop of paper, on which were printed a plurality of digits at regularly spaced intervals. The digits were integers that were generated by a specific algorithm. This band was capable of being used for "magic tricks" and also "to display various aspects of number theory." In the *Gulack* case, the Board had affirmed a rejection based on a prior art band that carried different indicia. The Board had given claim limitations about the printed digits no patentable weight. The Federal Circuit reversed the Board, holding that the claim limitations regarding the data could not be ignored in comparing the claim to the prior art. The Court held that the printed matter is to be considered to establish patentability if the printed matter is functionally related to the substrate on which it is printed. In the *Gulack* case, the Court found this functional relationship in that (1) the band "supports" the digits, and (2) there is an endless sequence of such digits with each digit in a unique position with respect to every other digit in the endless loop. This is similar to the claimed invention in the present application. The health information label supports the indicia specifying the health related information and the identity of the patient in the first and second areas, with the position and size of the first and second areas being such that the masking label can be applied over one or both of these areas to obscure the association between the identity of the patient and the health related information.

In re Ngai, 70 USPQ2d 1862 (Fed.Cir. 2004) is a recent Federal Circuit case, also dealing with the issue of printed matter, which interprets and explains *In re Gulack*. The Federal Circuit in *In re Ngai* held that the claim limitation of an instruction sheet packed with a prior art RNA testing kit was not a limitation that rendered the claim to the kit patentable, even though the method of use specified to be printed on the sheet was non-obvious. *In re Gulack* was distinguished by the Federal Circuit. The applicant, according to the *Ngai* Court, was entitled only to method claims on the new method of using the kit, not apparatus or article claims on the kit *per se*. Unlike the invention in *In re Ngai*, the invention in the present application contemplates printed matter that is funtionally related to the structure of the invention. The masking label is sized so that it can be applied over one or both of the first and second areas to obscure the association between the identity of the patient and the health related information.

Even if the claim limitations to the printed matter were ignored in the present application, nevertheless the claims would not be rendered obvious by the Blank reference. The Examiner

points to label 40 of Blank as corresponding the "masking label" of the claims. Actually reference numeral 40 refers to a "liner tab" which facilitates removal of the "label tab" which carries the confidential information, as shown in Fig. 3. The label tab can be destroyed after removal. There is no teaching in Blank of a "masking label" as called for in the claims that is to be applied over, or is capable of being applied over, one or both of the areas having name and health related information. What the Examiner points to as constituting the "masking label" of Blank actually carries the patient name and health information. It is therefore incapable of obscuring this patient name and health information.

Claim 6 has been rejected under 35 U.S.C. §103(a) as unpatentable over Blank in view of Stone et al (US 4,549,750). Claim 6 depends from claim 1 and is patentable over the Blank reference for the same reasons presented above with respect to claim 1. Stone does nothing to cure the defects of the rejection based on the Blank reference. Neither Blank nor Stone teaches a masking label as called for in the claim. Further, the combination of these references is clearly a matter of impermissible hindsight.

It is submitted that all of the claims currently presented in the instant application are in condition for allowance. The Examiner is encouraged to contact the undersigned to resolve efficiently any formal matters or to discuss any aspects of the application or of this response. Otherwise, early notification of allowable subject matter is respectfully solicited.

Respectfully submitted,

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